5 510(k) Summary

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Contact person Stephanie Coste

Date prepared 17 October 2008

Trade name RT041 Hospital Full Face Mask Non Vented[1]

Common name Face Mask

Classification name Continuous ventilator (accessory to)
Class II (21 CFR § 868.5895), product code CBK

Predicate device K060044 Fisher & Paykel Healthcare RT040 Acute Care Face Mask[2]

K023135 *Respironics Image3 SE Disposable Face Mask*[3] *(PerformaTrak SE)*

1 Referred to throughout this document as RT041

2 Referred to throughout this document as RT040

3 Note: To the best of our knowledge, the PerformaTrak SE is the currently marketed version of the Image3 SE originally approved under K023135. No approval number could be found for the PerformaTrak SE, which is why the original Image3 SE number is indicated in the predicate device section. Being the actual device available in the market, however, the PerformaTrak SE was used for testing and will be referred to as the predicate device throughout this document.

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5.1 Description

The purpose of the RT041 is to interface between a conventional mechanical ventilator (CBK) and the patient, delivering pressurized gasses to the nares and/or mouth of the patient. The mask interfaces with the patient's facial contours ensuring a good seal is achieved to deliver the pressurized gasses with minimal unintentional leakage. Some unintentional gas leak around the face is inevitable, however leak is minimized by a number of design features. The contoured shaping of the mask base and a soft, pliable facial seal improve closeness of fit to the skin. The headgear keeps the mask tight against the face and its soft, elastic fabric improves comfort. The glider and swivel elbow reduce pull from the tubing on the mask when the head moves. Pressure monitoring may be achieved by connecting a line to the pressure port on the mask.

5.2 Intended use

The RT041 is a patient interface for use as an accessory to a respiratory therapy device, i.e. ventilator that has adequate alarms and safety systems for ventilator failure, providing noninvasive positive pressure respiratory therapy. The mask is for single patient use with spontaneously breathing adult (> 30 kg) patients with respiratory insufficiency or respiratory failure who are suitable for noninvasive pressure support ventilation in hospital/institutional environments only.

5.3 Technological characteristics comparison

The RT041 is similar in shape to the RT040 using the same facial seal and headgear. The glider and quick release clip have different colors to differentiate between the models. Both the RT041 (CBK) and RT040 (MNT) are to be used with ventilators that have alarms and safety systems for ventilator failure. The RT040 mask has exhalation vents above the nasal bridge while the RT041 is non-vented.

Both the RT041 and PerformaTrak SE mask are to be used on CBK continuous ventilation systems and are both non-vented masks. Both indicate that they should have alarms and safety systems in case of ventilator failure.

5.4 Non-clinical tests

Comparative performance testing of the RT041 with the predicate masks RT040 & PerformaTrak SE show that the relevant features of each predicate are substantially equivalent.

5.5 Conclusion

The RT041 is substantially equivalent to the RT040 and PerformaTrak SE masks. The comparison of features, performance, materials and intended use demonstrate that the RT041 is at least as safe and effective for its intended purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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MAR 4 2009

Ms. Stephanie Coste
Regulatory Affairs Engineer
Respiratory Humidification
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P.O. Box 14 348, Panmure
Auckland, New Zealand

Re: K083122
Trade/Device Name: Fisher & Paykel Healthcare RT041 Hospital Full Face Mask Non Vented
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: February 3, 2009
Received: February 19, 2009

Dear Ms. Coste:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number

Device Name Fisher & Paykel Healthcare RT041 Hospital Full Face Mask Non Vented

The Fisher & Paykel Healthcare RT041 Hospital Full Face Mask Non Vented is a patient interface for use as an accessory to a respiratory therapy device, i.e. ventilator that has adequate alarms and safety systems for ventilator failure, providing noninvasive positive pressure respiratory therapy. The mask is for single patient use with spontaneously breathing adult (> 30 kg) patients with respiratory insufficiency or respiratory failure who are suitable for noninvasive pressure support ventilation in hospital/institutional environments only.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

K083122

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083122